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EXAMINER
SPIVACK, P

ART UNIT	PAPER NUMBER
1205	5

DATE MAILED: 12/27/95

12M2/1227
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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1 to 17 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1 to 17 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Claims 1 and 4 to 17 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a kidney disorder that is chronic renal failure. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The "kidney disorder" that is nephrolithiasis may not be associated with hyperphosphatemia. Undue experimentation would be required for one skilled in the art to ascertain which kidney disorders are appropriately included in the instant method of avoiding hyperphosphatemia in a patient having a kidney disorder comprising administering a vitamin D compound.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

While it would generally be accepted by one skilled in the art that vitamin D compounds suppress parathyroid hormone, the instant specification fails to provide guidelines as to determining which analogs of vitamin D will adversely affect calcium and phosphorus levels. There is no known vitamin D analog that is effective in suppressing hyperparathyroidism while

at the same time having a minimal effect on calcium and phosphorus levels. Thus, in view of the limited showing provided wherein only 19-nor-1,25-dihydroxyvitamin D_2 is disclosed as effective, undue experimentation would be required by one skilled in the art to determine which among a plethora of known vitamin D compound exhibit the desired effect of suppressing hyperparathyroidism while having a minimal effect on calcium and phosphorus levels and, therefore, may be used in a method of avoiding hyperphosphatemia and concurrently treating a kidney disorder.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1, 4 to 7 and 14 to 17 are rejected under 35 U.S.C. 103 as being unpatentable over both Lee et al., Proc. Workshop Vitam. D, and DeLuca et al., U. S. Patent No. 5,246,925. Lee

teaches the administration of the vitamin D compound 1,25-dihydroxyvitamin D_3 in the hyperphosphatemic state. DeLuca teaches the administration of the specific 19-nor-analogs of vitamin D in the treatment of the kidney disorder renal osteodystrophy. See column 1, lines 42-43 and 55. The claims differ in that Lee does not specifically discuss a renal disorder while DeLuca fails to teach the avoidance of hyperphosphatemia. However, one having ordinary skill in the art would have been motivated to seek a vitamin D compound for use in a method of avoiding hyperphosphatemia. Such would have been obvious in the absence of evidence to the contrary because the combined teachings of Lee, wherein hyperphosphatemia is avoided through administration of a particular vitamin D, and DeLuca, wherein a 19-nor-vitamin D compound, as required by claim 6, is used in the treatment of a kidney disorder, suggest the claimed invention. The dosage form most suitable for administration, as required by claims 4 and 5, as well as the form of administration and optimal dosage, as required by claims 14 to 17, would be within the purview of the skilled formulation chemist through no more than routine experimentation.

No claim is allowed.

Any inquiry concerning this communication from the Examiner should be directed to Phyllis Spivack whose telephone number is 703-308-4703. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703-308-1235.

SPIVACK

26 December 1995

Phyllis Spivack

PHYLLIS SPIVACK
PATENT EXAMINER
GROUP 120

Attachment _____

The drawings submitted with this application were declared informal by the applicant. Accordingly they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review.

Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.